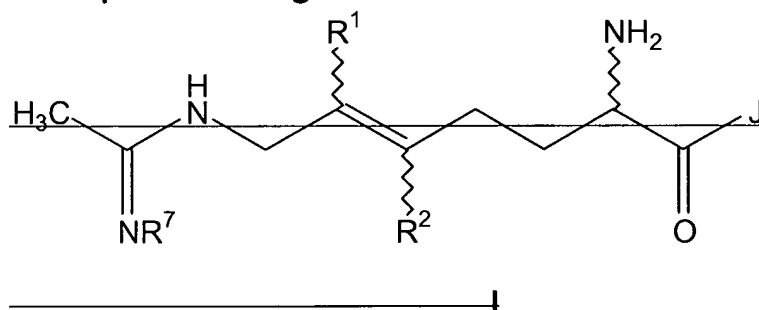


Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of the claims in the application:

Listing of Claims:

Claim 1 (currently amended) A method for the treatment ~~or prevention~~ of conditions or diseases of the gastrointestinal tract involving an overproduction of nitric oxide (NO) by inducible nitric oxide synthase (iNOS), in a subject in need of such treatment or prevention, said method comprising administering to the subject an anti-inflammatory effective amount of an inducible nitric oxide synthase selective inhibitor or pharmaceutically acceptable salt thereof or prodrug thereof, wherein the inducible nitric oxide synthase inhibitor is **selected from the group consisting of:**
a compound having Formula I



wherein:

~~R¹ is selected from the group consisting of H, halo and alkyl which may be optionally substituted by one or more halo;~~

~~R² is selected from the group consisting of H, halo and alkyl which may be optionally substituted by one or more halo;~~

~~with the proviso that at least one of R¹ or R² contains a halo;~~

~~R⁷ is selected from the group consisting of H and hydroxy;~~

~~J is selected from the group consisting of hydroxy, alkoxy, and NR^3R^4 wherein;~~

~~R^3 is selected from the group consisting of H, lower alkyl, lower alkylenyl and lower alkynyl;~~

~~R^4 is selected from the group consisting of H, and a heterocyclic ring in which at least one member of the ring is carbon and in which 1 to about 4 heteroatoms are independently selected from oxygen, nitrogen and sulfur and said heterocyclic ring may be optionally substituted with heteroaryl amino, N-aryl-N-alkyl amino, N-heteroaryl amino-N-alkyl amino, haloalkylthio, alkanoyloxy, alkoxy, heteroaralkoxy, cycloalkoxy, cycloalkenyloxy, hydroxy, amino, thio, nitro, lower alkyl amino, alkylthio, alkylthioalkyl, aryl amino, aralkyl amino, arylthio, alkylsulfinyl, alkylsulfonyl, alkylsulfonamido, alkylaminosulfonyl, amidosulfonyl, monoalkyl amidosulfonyl, dialkyl amidosulfonyl, monoarylamidosulfonyl, arylsulfonamido, diarylamidosulfonyl, monoalkyl monoaryl amidosulfonyl, arylsulfinyl, arylsulfonyl, heteroarylthio, heteroarylsulfinyl, heteroarylsulfonyl, alkanoyl, alkenoyl, aroyl, heteroaroyl, aralkanoyl, heteroaralkanoyl, haloalkanoyl, alkyl, alkenyl, alkynyl, alkylenedioxy, haloalkylenedioxy, cycloalkyl, cycloalkenyl, lower cycloalkylalkyl, lower cycloalkenylalkyl, halo, haloalkyl, haloalkoxy, hydroxyhaloalkyl, hydroxyaralkyl, hydroxyalkyl, hydroxyheteroaralkyl, haloalkoxyalkyl, aryl, aralkyl, aryloxy, aralkoxy, aryloxyalkyl, saturated heterocyclyl, partially saturated heterocyclyl, heteroaryl, heteroaryloxy, heteroaryloxyalkyl, arylalkyl, heteroarylalkyl, arylalkenyl, heteroarylalkenyl, cyanoalkyl, dicyanoalkyl, carboxamidoalkyl, dicarboxamidoalkyl, cyanocarboalkoxyalkyl, carboalkoxyalkyl, dicarboalkoxyalkyl, cyanocycloalkyl, dicyanocycloalkyl, carboxamidocycloalkyl, dicarboxamidocycloalkyl, carboalkoxycyanocycloalkyl, carboalkoxycycloalkyl, dicarboalkoxycycloalkyl, formylalkyl, acylalkyl, dialkoxyphosphonoalkyl, diaralkoxyphosphonoalkyl, phosphonoalkyl,~~

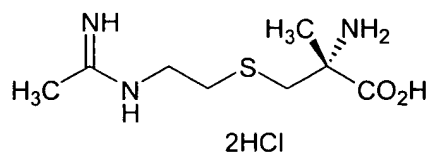
$$\begin{array}{c}
 \text{R}^{23} \quad \text{R}^{22} \quad \text{R}^{20} \quad \text{R}^{11} \quad \text{R}^{16} \quad \text{R}^{12} \quad \text{O} \\
 \diagdown \quad | \quad | \quad | \quad | \quad | \quad // \\
 \text{C} = \text{N} - \text{C} - \text{C} - \text{C} - \text{C} - \text{C} - \text{C} \\
 \diagup \quad | \quad | \quad | \quad | \quad | \quad \diagdown \\
 \text{R}^{21} \quad \text{R}^{19} \quad \text{R}^{17} \quad \text{X} \quad \text{R}^{15} \quad \text{R}^{14} \quad \text{R}^{13} \quad \text{R}^{18}
 \end{array}$$

II

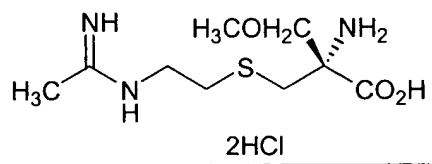
-5-

consisting of -H, -OH, -C(O)-O-R³⁴, and -C(O)-S-R³⁵, and R²² is selected from the group consisting of -H, -OH, -C(O)-O-R³⁶, and -C(O)-S-R³⁷; or R²¹ is -O-, and R²² is -C(O)-, wherein R²¹ and R²² together with the atoms to which they are attached form a ring; or R²¹ is -C(O)-, and R²² is -O-, wherein R²¹ and R²² together with the atoms to which they are attached form a ring, R²³ is C₁ alkyl, R²⁴ is selected from the group consisting of -H and C₁-C₆ alkyl, wherein when R²⁴ is C₁-C₆ alkyl, R²⁴ is optionally substituted by one or more moieties selected from the group consisting of cycloalkyl, heterocyclyl, aryl, and heteroaryl, R²⁵ is selected from the group consisting of -H, alkyl, and alkoxy, and R²⁶ is selected from the group consisting of -H, -OH, alkyl, alkoxy, -C(O)-R³⁸, -C(O)-O-R³⁹, and -C(O)-S-R⁴⁰; wherein when R²⁵ and R²⁶ independently are alkyl or alkoxy, R²⁵ and R²⁶ independently are optionally substituted with one or more moieties selected from the group consisting of cycloalkyl, heterocyclyl, aryl, and heteroaryl; or R²⁵ is -H; and R²⁶ is selected from the group consisting of cycloalkyl, heterocyclyl, aryl, and heteroaryl, R²⁷, R²⁸, R²⁹, R³⁰, R³¹, R³², R³³, R³⁴, R³⁵, R³⁶, R³⁷, R³⁸, R³⁹, and R⁴⁰ independently are selected from the group consisting of -H and alkyl, wherein alkyl is optionally substituted by one or more moieties selected from the group consisting of cycloalkyl, heterocyclyl, aryl, and heteroaryl, wherein when any of R¹¹, R¹², R¹³, R¹⁴, R¹⁵, R¹⁶, R¹⁷, R¹⁸, R¹⁹, R²⁰, R²¹, R²², R²³, R²⁴, R²⁵, R²⁶, R²⁷, R²⁸, R²⁹, R³⁰, R³¹, R³², R³³, R³⁴, R³⁵, R³⁶, R³⁷, R³⁸, R³⁹, and R⁴⁰ independently is a moiety selected from the group consisting of alkyl, alkenyl, alkynyl, alkoxy, alkylthio, cycloalkyl, heterocyclyl, aryl, and heteroaryl, then the moiety is optionally substituted by one or more substituent selected from the group consisting of -OH, alkoxy, and halogen;

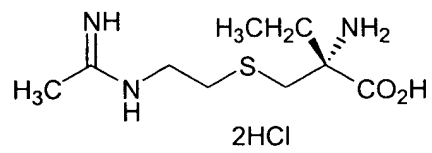
and wherein the compound is selected from the group consisting of:



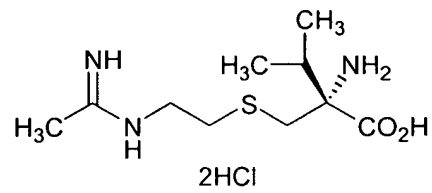
S-[2-[(1-Iminoethyl)amino]ethyl]-2-methyl-L-cysteine, dihydrochloride;



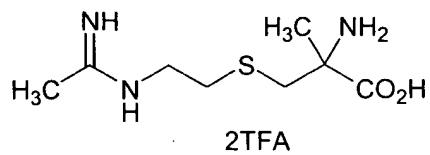
**2-[[[2-[(1-Iminoethyl)amino]ethyl]thio]methyl]-O-methyl-D-serine,
dihydrochloride;**



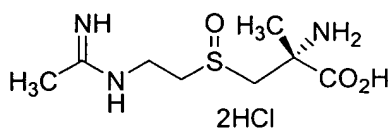
S-[2-[(1-Iminoethyl)amino]ethyl]-2-ethyl-L-cysteine, dihydrochloride;



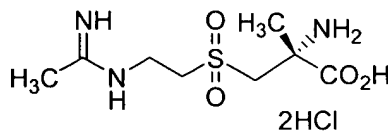
2-[[[2-(1-Iminoethyl)amino]ethyl]thio]methyl]-D-valine, dihydrochloride;



S-[2-(1-iminoethylamino)ethyl]-2-methyl-(D/L)-cysteine, bistrifluoroacetate;

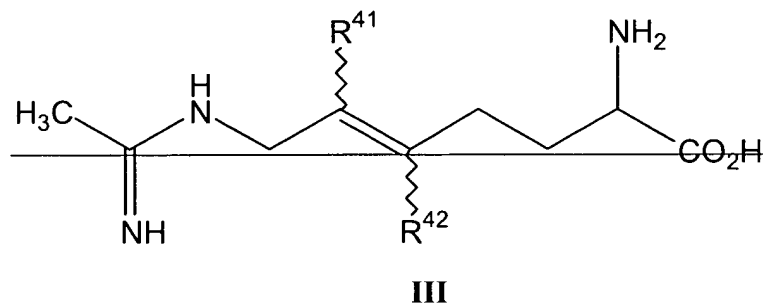


(2R)-2-Amino-3[[2-[(1-iminoethyl)amino]ethyl]sulfinyl]-2-methylpropanoic acid, dihydrochloride; and



(2R)-2-Amino-3[[2-[(1-iminoethyl)amino]ethyl]sulfonyl]-2-methylpropanoic acid dihydrochloride,

-a compound represented by Formula III

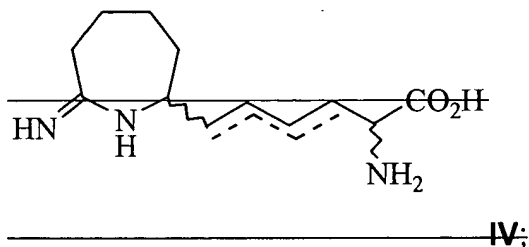


wherein:

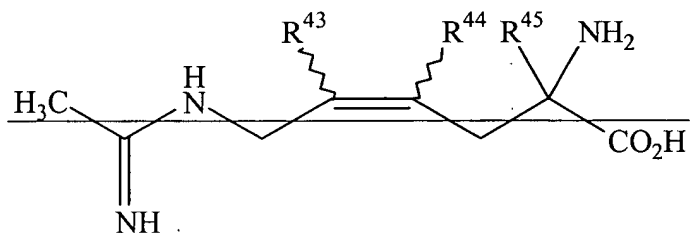
R⁴¹ is H or methyl; and

R^{42} is H or methyl;

a compound of formula **IV**:



a compound of Formula **V**:



V

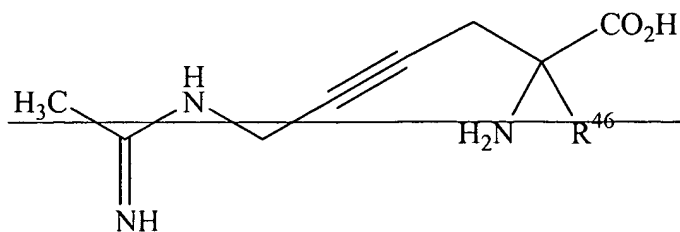
wherein:

R^{43} is selected from the group consisting of hydrogen, halo, C_4 - C_5 alkyl and C_4 - C_5 alkyl substituted by alkoxy or one or more halo;

R^{44} is selected from the group consisting of hydrogen, halo, C_4 - C_5 alkyl and C_4 - C_5 alkyl substituted by alkoxy or one or more halo;

R^{45} is C_4 - C_5 alkyl or C_4 - C_5 alkyl be substituted by alkoxy or one or more halo;

a compound of Formula **VI**:

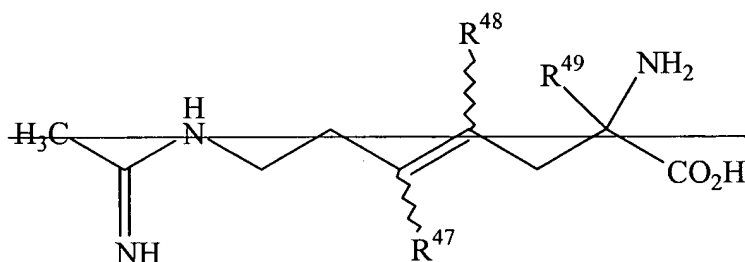


VI

wherein:

~~R⁴⁶ is C₄-C₅ alkyl, said C₄-C₅ alkyl optionally substituted by halo or alkoxy, said alkoxy optionally substituted by one or more halo;~~

~~a compound of Formula VII~~



VII

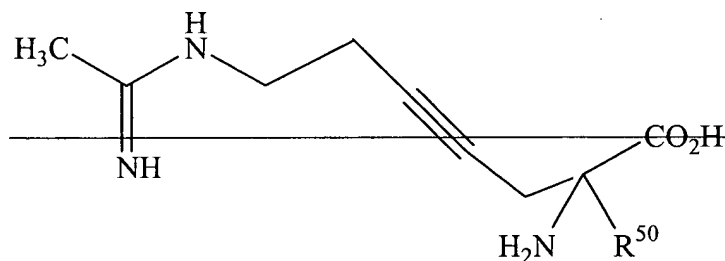
wherein:

~~R⁴⁷ is selected from the group consisting of hydrogen, halo, C₄-C₅ alkyl and C₄-C₅ alkyl substituted by alkoxy or one or more halo;~~

~~R⁴⁸ is selected from the group consisting of hydrogen, halo, C₄-C₅ alkyl and C₄-C₅ alkyl substituted by alkoxy or one or more halo;~~

~~R⁴⁹ is C₄-C₅ alkyl or C₄-C₅ alkyl substituted by alkoxy or one or more halo;~~

~~a compound of Formula VIII~~

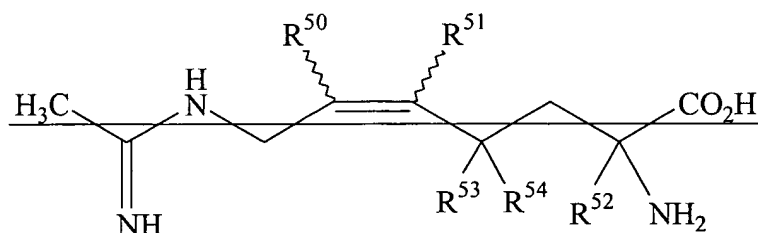


VIII

wherein:

~~R⁵⁰ is C₄-C₅ alkyl, said C₄-C₅ alkyl optionally substituted by halo or alkoxy, said alkoxy optionally substituted by one or more halo;~~

~~a compound of formula IX~~



~~IX~~

~~wherein:~~

~~R⁵⁰ is selected from the group consisting of hydrogen, halo, and C₄-C₅ alkyl, said C₄-C₅ alkyl optionally substituted by halo or alkoxy, said alkoxy optionally substituted by one or more halo;~~

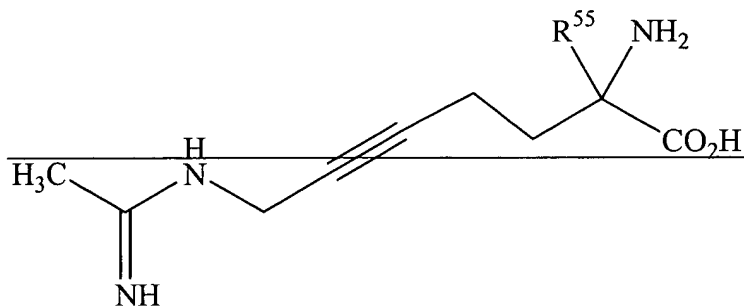
~~R⁵¹ is selected from the group consisting of hydrogen, halo, and C₄-C₅ alkyl, said C₄-C₅ alkyl optionally substituted by halo or alkoxy, said alkoxy optionally substituted by one or more halo;~~

~~R⁵² is C₄-C₅ alkyl, said C₄-C₅ alkyl optionally substituted by halo or alkoxy, said alkoxy optionally substituted by one or more halo;~~

~~R⁵³ is selected from the group consisting of hydrogen, halo, and C₄-C₅ alkyl, said C₄-C₅ alkyl optionally substituted by halo or alkoxy, said alkoxy optionally substituted by one or more halo; and~~

~~R⁵⁴ is selected from the group consisting of halo and C₄-C₅ alkyl, said C₄-C₅ alkyl optionally substituted by halo or alkoxy, said alkoxy optionally substituted by one or more halo;~~

~~a compound of formula X~~

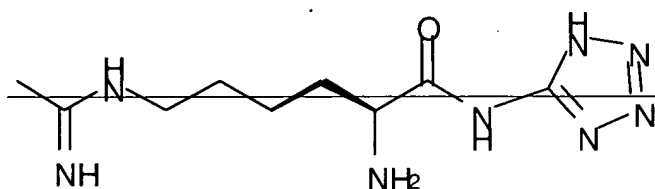


X

wherein:

~~R⁵⁵ is C₄-C₅ alkyl, said C₄-C₅ alkyl optionally substituted by halo or alkoxy, said alkoxy optionally substituted by one or more halo.~~

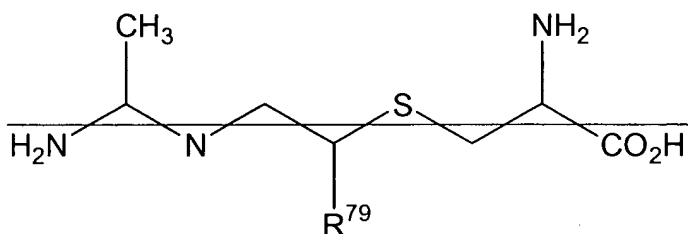
~~— a compound having the formula XI —.~~



~~2S-amino-6-[(1-iminoethyl)amino]-N-(1H-tetrazol-5-yl)-hexanamide, hydrate, dihydrochloride~~

XI

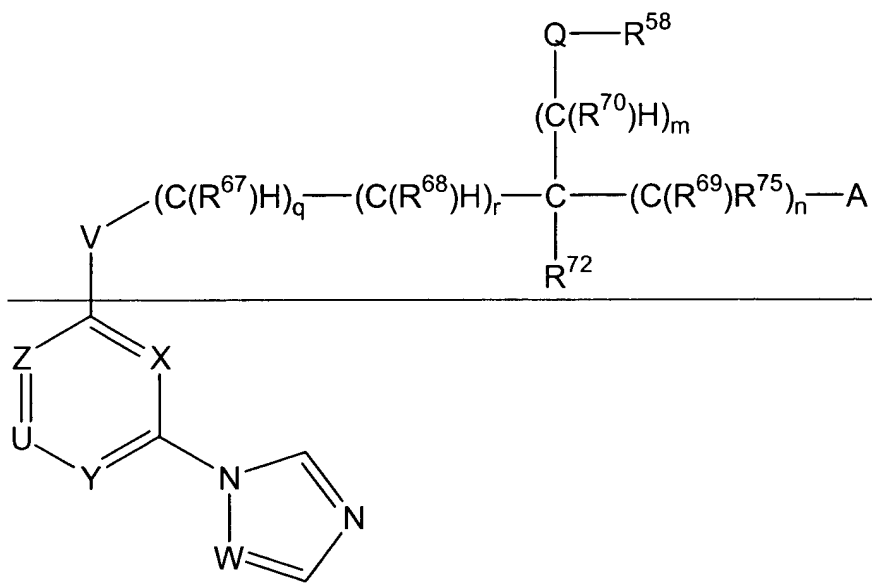
~~A compound of formula XII:~~



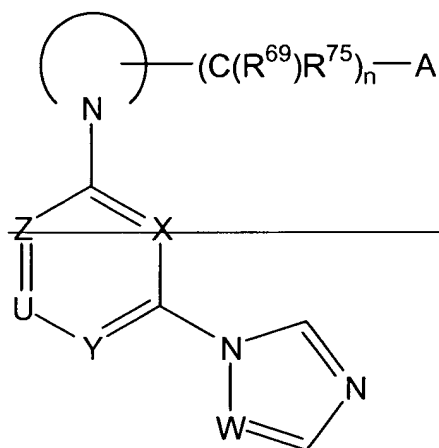
XII

~~wherein R⁷⁹ is selected from C₁₋₄ alkyl, C₃₋₄ cycloalkyl, C₁₋₄ hydroxyalkyl, and C₁₋₄ haloalkyl;~~

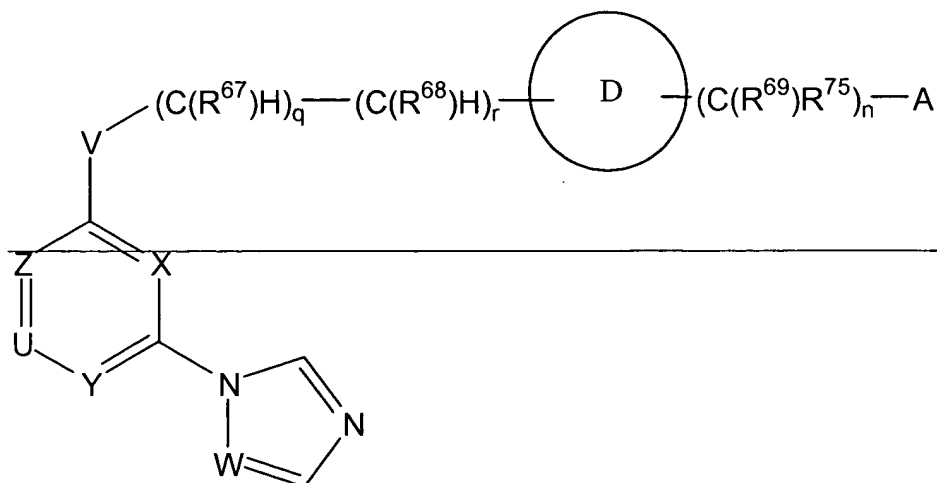
~~a compound of Formula XIII, Formula XIV or Formula XV:~~



Formula XIII;



Formula XIV; or



Formula XV;

wherein:

A is R^{56} , OR^{56} , $\text{C(O)N(R}^{56}\text{)R}^{57}$, $\text{P(O)[N(R}^{56}\text{)R}^{57}]_2$, $\text{N(R}^{56}\text{)C(O)R}^{57}$,
 $\text{N(R}^{76}\text{)C(O)OR}^{56}$, $\text{N(R}^{56}\text{)R}^{76}$,
 $\text{N(R}^{74}\text{)C(O)N(R}^{56}\text{)R}^{74}$, $\text{S(O)}_t\text{R}^{56}$, $\text{SO}_2\text{NHC(O)R}^{56}$, $\text{NHSO}_2\text{R}^{77}$,
 $\text{SO}_2\text{NH(R}^{56}\text{)H}$, $\text{C(O)NHSO}_2\text{R}^{77}$, and CH-NOR^{56} ;

each X, Y and Z are independently N or $\text{C(R}^{49}\text{)}$;

each U is N or $\text{C(R}^{60}\text{)}$, provided that U is N only when X is N and Z and Y are
 CR^{74} ;

V is $\text{N(R}^{59}\text{)}$, S, O or $\text{C(R}^{59}\text{)H}$;

Each W is N or CH;

Q is chosen from the group consisting of a direct bond, C(O) , O , $\text{C(=N-R}^{56}\text{)}$,
 S(O)_t , and $\text{N(R}^{64}\text{)}$;

m is zero or an integer from 1 to 4;

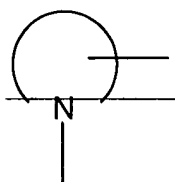
n is zero or an integer from 1 to 3;

q is zero or one;

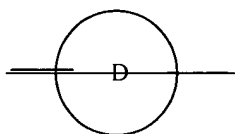
r is zero or one, provided that when Q and V are heteroatoms, m, q, and r cannot
 all be zero;

when A is OR^{56} , $\text{N(R}^{56}\text{)C(O)R}^{57}$, $\text{N(R}^{74}\text{)C(O)OR}^{57}$, $\text{N(R}^{56}\text{)R}^{76}$,
 $\text{N(R}^{74}\text{)C(O)N(R}^{56}\text{)R}^{74}$, $\text{S(O)}_t\text{R}^{56}$ (where t is zero), or $\text{NHSO}_2\text{R}^{77}$, n, q, and r

cannot all be zero; and when Q is a heteroatom and A is OR^{56} , $\text{N(R}^{56})\text{C(O)R}^{57}$, $\text{N(R}^{71})\text{C(O)OR}^{57}$, $\text{N(R}^{56})\text{R}^{76}$, $\text{N(R}^{71})\text{C(O)N(R}^{56})\text{R}^{71}$, $\text{S(O)}_t\text{R}^{56}$ (when t is zero), or $\text{NH}\text{SO}_2\text{R}^{77}$, m and n cannot both be zero; t is zero, one or two;



is an optionally substituted N-heterocyclyl;



is an optionally substituted carbocyclyl or optionally substituted N-heterocyclyl;

each R^{56} and R^{57} are independently chosen from the group consisting of hydrogen, optionally substituted $\text{C}_1\text{--C}_{20}$ alkyl, optionally substituted cycloalkyl, $[\text{C}_0\text{--C}_8\text{ alkyl}]\text{R}^{64}$, $[\text{C}_2\text{--C}_8\text{ alkenyl}]\text{R}^{64}$, $[\text{C}_2\text{--C}_8\text{ alkynyl}]\text{R}^{64}$, $[\text{C}_2\text{--C}_8\text{ alkyl}]\text{R}^{65}$ (optionally substituted by hydroxy), $[\text{C}_4\text{--C}_8]\text{R}^{66}$ (optionally substituted by hydroxy), optionally substituted heterocyclyl;

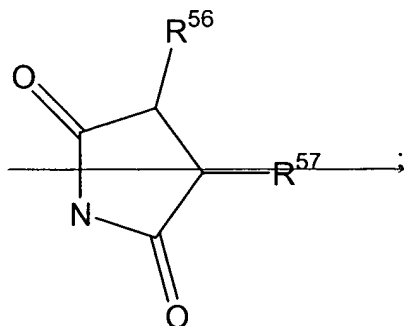
or R^{56} and R^{57} together with the nitrogen atom to which they are attached is an optionally substituted N-heterocyclyl;

R^{58} is chosen from the group consisting of hydrogen, alkyl, cycloalkyl, optionally substituted aryl, haloalkyl, $[\text{C}_4\text{--C}_8\text{ alkyl}]\text{C(O)N(R}^{56})\text{R}^{57}$, $[\text{C}_4\text{--C}_8\text{ alkyl}]\text{N(R}^{56})\text{R}^{57}$, $[\text{C}_4\text{--C}_8\text{ alkyl}]\text{R}^{63}$, $[\text{C}_2\text{--C}_8\text{ alk2yl}]\text{R}^{65}$, $[\text{C}_4\text{--C}_8\text{ alkyl}]\text{R}^{66}$, and heterocyclyl (optionally substituted by one or more substituents selected from the group consisting of halo, alkyl, alkoxy and imidazolyl);

or when Q is $\text{N(R}^{58})$ or a direct bond to R^{58} , R^{58} may additionally be aminocarbonyl,

alkoxycarbonyl, alkylsulfonyl, monoalkylaminocarbonyl, dialkylaminocarbonyl and $\text{C(=NR}^{73})\text{NH}_2$;

or ~~Q-R⁵⁸ taken together represents C(O)OH, C(O)N(R⁵⁶)R⁵⁷ or~~



~~R⁵⁹ is chosen from the group consisting of hydrogen, alkyl, aryl, aralkyl and cycloalkyl;~~

~~Provided that when A is R⁵⁶ or OR⁵⁶, R⁵⁹ cannot be hydrogen, and when V is CH, R⁵⁹ may additionally be hydroxy;~~

~~R⁶⁰ is chosen from the group consisting of hydrogen, alkyl, aryl, aralkyl, haloalkyl, optionally substituted aralkyl, optionally substituted aryl, OR⁷⁴, S(O)_tR⁷⁴, N(R⁷⁴)R⁷⁶, N(R⁷⁴)C(O)N(R⁵⁶)R⁷⁴, N(R⁷⁴)C(O)OR⁷⁴, N(R⁷⁴)C(O)R⁷⁴, [C₀-C₈ alkyl]-C(H)[C(O)R⁷⁴]₂ and [C₀-C₈ alkyl]-C(O)N(R⁵⁶)R⁷⁴;~~

~~R⁶¹ is chosen from the group consisting of hydrogen, alkyl, cycloalkyl, [C₄-C₈ alkyl]-R⁶³, [C₂-C₈ alkyl]-R⁶⁵, [C₄-C₈ alkyl]-R⁶⁶, acyl, C(O)R⁶³, C(O)-[C₄-C₈ alkyl]-R⁶³, alkoxycarbonyl, optionally substituted aryloxy carbonyl, optionally substituted aralkoxycarbonyl, alkylsulfonyl, optionally substituted aryl, optionally substituted heterocyclyl, alkoxycarbonylalkyl, carboxyalkyl, optionally substituted arylsulfonyl, aminocarbonyl, monoalkylaminocarbonyl, dialkylaminocarbonyl, optionally substituted arylaminocarbonyl, aminosulfonyl, monoalkylaminosulfonyl, dialkylaminosulfonyl, arylaminosulfonyl, arylsulfonylaminocarbonyl, optionally substituted N-heterocyclyl, C(=NH)-N(CN)R⁵⁶, C(O)R⁷⁸-N(R⁵⁶)R⁵⁷, C(O)-N(R⁵⁶)R⁷⁸-C(O)OR⁵⁶;~~

~~each R⁶³ and R⁶⁴ are independently chosen from the group consisting of haloalkyl,~~

~~cycloalkyl, (optionally substituted with halo, cyano, alkyl or alkoxy), carbocyclyl (optionally substituted with one or more substituents selected from the group~~

~~consisting of halo, alkyl and alkoxy) and heterocyclyl (optionally substituted with alkyl, aralkyl or alkoxy);~~

~~each R⁶⁵ is independently chosen from the group consisting of halo, alkoxy, optionally~~

~~substituted aryloxy, optionally substituted aralkoxy, optionally substituted S(O)_t, R⁷⁷, acylamino, amino, monoalkylamino, dialkylamino, (triphenylmethyl)amino, hydroxy, mercapto, alkylsulfonamido;~~

~~each R⁶⁶ is independently chosen from the group consisting of cyano, di(alkoxy)alkyl,~~

~~carboxy, alkoxycarbonyl, aminocarbonyl, monoalkylaminocarbonyl and dialkylaminocarbonyl;~~

~~each R⁶⁷, R⁶⁸, R⁶⁹, R⁷⁰, R⁷², and R⁷⁵ are independently hydrogen or alkyl;~~

~~each R⁷⁴ is independently hydrogen, alkyl, optionally substituted aryl, optionally substituted aralkyl or cycloalkyl;~~

~~R⁷³ is hydrogen, NO₂, or toluenesulfonyl;~~

~~each R⁷⁴ is independently hydrogen, alkyl (optionally substituted with hydroxy), cyclopropyl, halo or haloalkyl;~~

~~each R⁷⁶ is independently hydrogen, alkyl, cycloalkyl, optionally substituted aryl, optionally substituted aralkyl, C(O)R⁷⁷ or SO₂R⁷⁷;~~

~~or R⁷⁶ taken together with R⁵⁶ and the nitrogen to which they are attached is an optionally~~

~~substituted N-heterocyclyl;~~

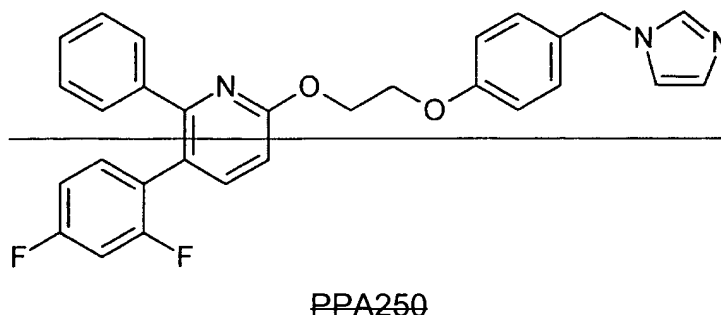
~~or R⁷⁶ taken together with R⁷⁴ and the nitrogen to which they are attached is an optionally~~

~~substituted N-heterocyclyl;~~

~~each R⁷⁷ is independently alkyl, cycloalkyl, optionally substituted aryl or optionally substituted aralkyl; and~~

~~R⁷⁸ is an amino acid residue; and~~

____ PPA250



or a pharmaceutically acceptable salt or prodrug of any of said inducible nitric oxide synthase inhibitors.

Claim 2 (original) The method of claim 1 wherein the condition or disease of the gastrointestinal tract is selected from the group consisting of inflammatory bowel disease, Crohn's disease, ulcerative colitis, peptic ulcer disease, gastric ulceration, duodenal ulceration, gastritis, ileitis, gastroesophageal reflux disease, irritable bowel syndrome, paralytic ileus and diarrhea.

Claim 3 (original) The method of claim 1 wherein the condition or disease of the gastrointestinal tract is inflammatory bowel disease.

Claim 4 (original) The method of claim 1 wherein the condition or disease of the gastrointestinal tract is Crohn's disease.

Claim 5 (original) The method of claim 1 wherein the condition or disease of the gastrointestinal tract is ulcerative colitis.

Claim 6 (original) The method of claim 1 wherein the condition or disease of the gastrointestinal tract is gastritis.

Claim 7 (original) The method of claim 1 wherein the condition or disease of the gastrointestinal tract is ileitis.

Claim 8 (original) The method of claim 1 wherein the condition or disease of the gastrointestinal tract is peptic ulceration.

Claim 9 (original) The method of claim 8 wherein the condition or disease of the gastrointestinal tract is gastric ulceration.

Claim 10 (original) The method of claim 8 wherein the condition or disease of the gastrointestinal tract is duodenal ulceration.

Claim 11 (original) The method of claim 1 wherein the condition or disease of the gastrointestinal tract is esophagitis.

Claim 12 (original) The method of claim 1 wherein the condition or disease of the gastrointestinal tract is gastroesophageal reflux disease.

Claim 13 (original) The method of claim 1 wherein the condition or disease of the gastrointestinal tract is irritable bowel syndrome.

Claim 14 (original) The method of Claim 1 wherein the condition or disease of the gastrointestinal tract is selected from group consisting of peptic ulcer disease and gastritis, said method further comprising administering to the subject an amount of an antimicrobial compound or pharmaceutically acceptable salt thereof or prodrug thereof, wherein the amount of the inducible nitric oxide synthase selective inhibitor and the amount of the antimicrobial compound together constitute an amount effective against the condition or disease of the gastrointestinal tract.

Claim 15 (original) The method of Claim 14 wherein the antimicrobial compound comprises an antibiotic compound.

Claim 16 (original) The method of Claim 14 wherein the antimicrobial compound comprises at least one compound selected from the group consisting of the following: amoxicillin, clarithromycin, rifabutin, bismuth subsalicylate, metronidazole, and tetracycline.

Claim 17 (original) The method of Claim 1 further comprising administering to the subject an amount of an antisecretory compound or pharmaceutically acceptable salt thereof or prodrug thereof, wherein the amount of the inducible nitric oxide synthase selective inhibitor and the amount of the antisecretory compound together constitute an amount effective against the condition or disease of the gastrointestinal tract.1

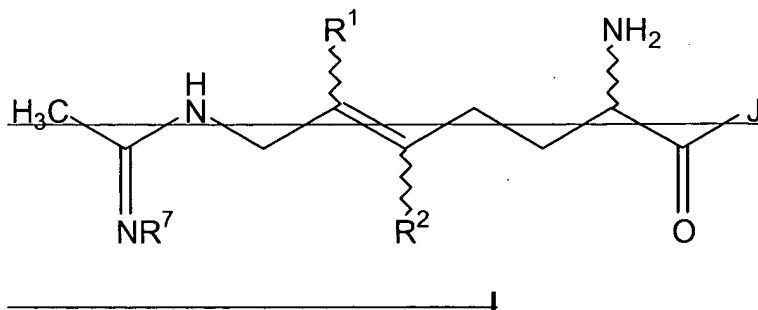
Claim 18 (original) The method of Claim 17 wherein the antisecretory compound comprises a proton-pump inhibitor.

Claim 19 (original) The method of Claim 17 wherein the antisecretory compound comprises omeprazole.

Claim 20 (original) The method of Claim 17 wherein the antisecretory compound comprises an H₂-receptor antagonist.

Claim 21 (original) The method of Claim 20 wherein the antisecretory compound comprises ranitidine.

Claim 22. (currently amended) A method for the treatment ~~or prevention~~ of inflammatory conditions or diseases of the gastrointestinal tract involving an overproduction of nitric oxide (NO) by inducible nitric oxide synthase (iNOS) and microbial infection, in a subject in need of such treatment or prevention, said method comprising administering to the subject an amount of an inducible nitric oxide synthase selective inhibitor or pharmaceutically acceptable salt thereof or prodrug thereof, and an amount of an antimicrobial compound or pharmaceutically acceptable salt thereof or prodrug thereof, wherein the amount of the inducible nitric oxide synthase selective inhibitor and the amount of the antibiotic compound together constitute an amount effective against the condition or disease of the gastrointestinal tract, wherein the inducible nitric oxide synthase inhibitor is ~~selected from the group consisting of:~~
~~a compound having Formula I~~



wherein:

~~R¹ is selected from the group consisting of H, halo and alkyl which may be optionally substituted by one or more halo;~~

~~R² is selected from the group consisting of H, halo and alkyl which may be optionally substituted by one or more halo;~~

~~with the proviso that at least one of R¹ or R² contains a halo;~~

~~R⁷ is selected from the group consisting of H and hydroxy;~~

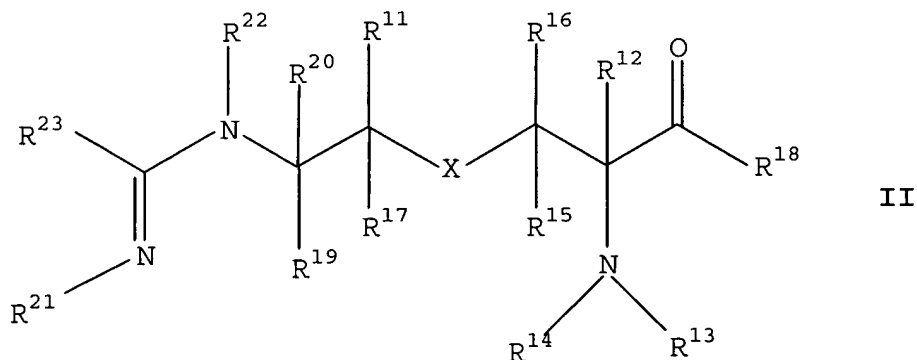
~~J is selected from the group consisting of hydroxy, alkoxy, and NR³R⁴ wherein;~~

~~R³ is selected from the group consisting of H, lower alkyl, lower alkylenyl and lower alkynyl;~~

~~R⁴ is selected from the group consisting of H, and a heterocyclic ring in which at least one member of the ring is carbon and in which 1 to about 4 heteroatoms are independently selected from oxygen, nitrogen and sulfur and said heterocyclic ring may be optionally substituted with heteroaryl amino, N-aryl-N-alkyl amino, N-heteroaryl amino-N-alkyl amino, haloalkylthio, alkanoyloxy, alkoxy, heteroaralkoxy, cycloalkoxy, cycloalkenyloxy, hydroxy, amino, thio, nitro, lower alkyl amino, alkylthio, alkylthioalkyl, aryl amino, aralkyl amino, arylthio, alkylsulfinyl, alkylsulfonyl, alkylsulfonamido, alkylaminosulfonyl, amidosulfonyl, monoalkyl amidosulfonyl, dialkyl amidosulfonyl, monoaryl amidosulfonyl, arylsulfonamido, diaryl amidosulfonyl, monoalkyl monoaryl amidosulfonyl, arylsulfinyl, arylsulfonyl, heteroarylthio, heteroarylsulfinyl,~~

~~heteroarylsulfonyl, alkanoyl, alkenoyl, aroyl, heteroaroyl, aralkanoyl, heteroaralkanoyl, haloalkanoyl, alkyl, alkenyl, alkynyl, alkylenedioxy, haloalkylenedioxy, cycloalkyl, cycloalkenyl, lower cycloalkylalkyl, lower cycloalkenylalkyl, halo, haloalkyl, haloalkoxy, hydroxyhaloalkyl, hydroxyaralkyl, hydroxyalkyl, hydroxyheteroaralkyl, haloalkoxyalkyl, aryl, aralkyl, aryloxy, aralkoxy, aryloxyalkyl, saturated heterocyclyl, partially saturated heterocyclyl, heteroaryl, heteroaryloxy, heteroaryloxyalkyl, arylalkyl, heteroarylalkyl, arylalkenyl, heteroarylalkenyl, cyanoalkyl, dicyanoalkyl, carboxamidoalkyl, dicarboxamidoalkyl, cyanocarboalkoxyalkyl, carboalkoxyalkyl, dicarboalkoxyalkyl, cyanocycloalkyl, dicyanocycloalkyl, carboxamidocycloalkyl, dicarboxamidocycloalkyl, carboalkoxycyanocycloalkyl, carboalkoxycycloalkyl, dicarboalkoxycycloalkyl, formylalkyl, acylalkyl, dialkoxyposphonoalkyl, diaralkoxyposphonoalkyl, phosphonoalkyl, dialkoxyposphonoalkoxy, diaralkoxyposphonoalkoxy, phosphonoalkoxy, dialkoxyposphonoalkylamino, diaralkoxyposphonoalkylamino, phosphonoalkylamino, dialkoxyposphonoalkyl, diaralkoxyposphonoalkyl, guanidino, amidino, and acylamino;~~

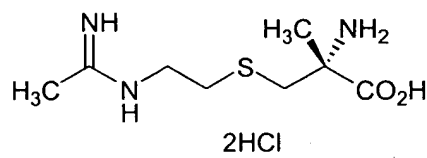
a compound having a structure corresponding to Formula II



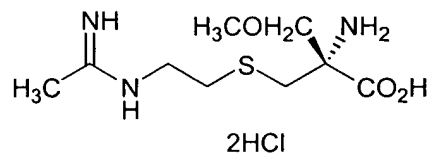
wherein X is selected from the group consisting of -S-, -S(O)-, and -S(O)₂-, R¹² is selected from the group consisting of C₁-C₆ alkyl, C₂-C₆ alkenyl, C₂-C₆ alkynyl, C₁-C₅ alkoxy-C₁ alkyl, and C₁-C₅ alkylthio-C₁ alkyl wherein each of these groups is optionally substituted by one or more substituent selected from the group consisting of -OH, alkoxy, and halogen, R¹⁸ is selected from the group consisting of -OR²⁴ and -N(R²⁵)(R²⁶), and R¹³ is selected from the group consisting of -H, -OH, -C(O)-R²⁷, -C(O)-O-R²⁸, and -C(O)-S-R²⁹; or R¹⁸ is -N(R³⁰)-, and R¹³ is -C(O)-, wherein R¹⁸ and R¹³ together with the atoms to which they are attached form a ring; or R¹⁸ is -O-, and R¹³ is -C(R³¹)(R³²)-, wherein R¹⁸ and R¹³ together with the atoms to which they are attached form a ring, wherein if R¹³ is -C(R³¹)(R³²)-, then R¹⁴ is -C(O)-O-R³³; otherwise R¹⁴ is -H, R¹¹, R¹⁵, R¹⁶, and R¹⁷ independently are selected from the group consisting of -H, halogen, C₁-C₆ alkyl, C₂-C₆ alkenyl, C₂-C₆ alkynyl, and C₁-C₅ alkoxy-C₁ alkyl, R¹⁹ and R²⁰ independently are selected from the group consisting of -H, C₁-C₆ alkyl, C₂-C₆ alkenyl, C₂-C₆ alkynyl, and C₁-C₅ alkoxy-C₁ alkyl, R²¹ is selected from the group consisting of -H, -OH, -C(O)-O-R³⁴, and -C(O)-S-R³⁵, and R²² is selected from the group consisting of -H, -OH, -C(O)-O-R³⁶, and -C(O)-S-R³⁷; or R²¹ is -O-, and R²² is -C(O)-, wherein R²¹ and R²² together with the atoms to which they are attached form a ring; or R²¹ is -C(O)-, and R²² is -O-, wherein R²¹ and R²² together with the atoms to which they are attached form a ring, R²³ is C₁ alkyl, R²⁴ is selected from the group consisting of -H and C₁-C₆ alkyl, wherein when R²⁴ is C₁-C₆ alkyl, R²⁴ is optionally substituted by one or more moieties selected from the group consisting of cycloalkyl, heterocyclyl, aryl, and heteroaryl, R²⁵ is selected from the group consisting of -H, alkyl, and alkoxy, and R²⁶ is selected from the group consisting of -H, -OH, alkyl, alkoxy, -C(O)-R³⁸, -C(O)-O-R³⁹, and -C(O)-S-R⁴⁰; wherein when R²⁵ and R²⁶ independently are alkyl or alkoxy, R²⁵ and R²⁶ independently are optionally substituted with one or more moieties selected from the group consisting of cycloalkyl, heterocyclyl, aryl, and heteroaryl; or R²⁵ is -H; and R²⁶ is selected from the group consisting of cycloalkyl, heterocyclyl, aryl, and heteroaryl, R²⁷, R²⁸, R²⁹, R³⁰, R³¹, R³², R³³, R³⁴, R³⁵, R³⁶, R³⁷, R³⁸, R³⁹, and R⁴⁰

independently are selected from the group consisting of -H and alkyl, wherein alkyl is optionally substituted by one or more moieties selected from the group consisting of cycloalkyl, heterocyclyl, aryl, and heteroaryl, wherein when any of R^{11} , R^{12} , R^{13} , R^{14} , R^{15} , R^{16} , R^{17} , R^{18} , R^{19} , R^{20} , R^{21} , R^{22} , R^{23} , R^{24} , R^{25} , R^{26} , R^{27} , R^{28} , R^{29} , R^{30} , R^{31} , R^{32} , R^{33} , R^{34} , R^{35} , R^{36} , R^{37} , R^{38} , R^{39} , and R^{40} independently is a moiety selected from the group consisting of alkyl, alkenyl, alkynyl, alkoxy, alkylthio, cycloalkyl, heterocyclyl, aryl, and heteroaryl, then the moiety is optionally substituted by one or more substituent selected from the group consisting of -OH, alkoxy, and halogen;

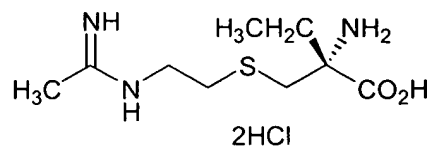
and wherein the compound is selected from the group consisting of:



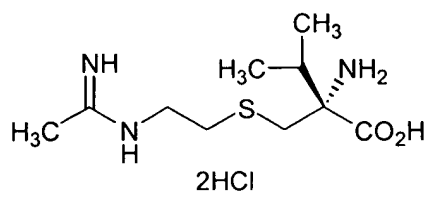
S-[2-[(1-iminoethyl)amino]ethyl]-2-methyl-L-cysteine, dihydrochloride;



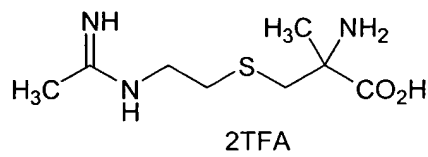
**2-[[[2-[(1-iminoethyl)amino]ethyl]thio]methyl]-O-methyl-D-serine,
dihydrochloride;**



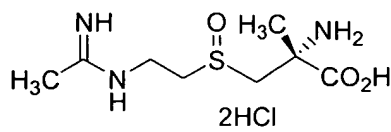
S-[2-[(1-Iminoethyl)amino]ethyl]-2-ethyl-L-cysteine, dihydrochloride;



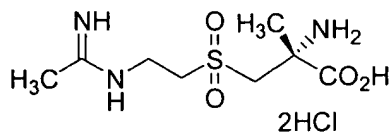
2-[[[2-(1-Iminoethyl)amino]ethyl]thio]methyl]-D-valine, dihydrochloride;



S-[2-(1-Iminoethylamino)ethyl]-2-methyl-(D/L)-cysteine, bistrifluoroacetate;

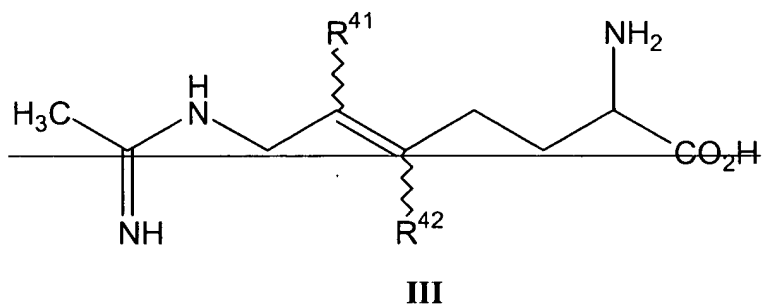


(2R)-2-Amino-3[[2-[(1-iminoethyl)amino]ethyl]sulfinyl]-2-methylpropanoic acid, dihydrochloride; and



(2R)-2-Amino-3[[2-[(1-iminoethyl)amino]ethyl]sulfonyl]-2-methylpropanoic acid dihydrochloride,

~~a compound represented by Formula III~~

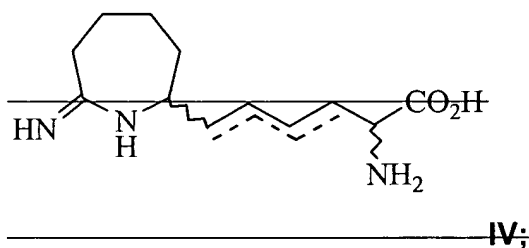


wherein:

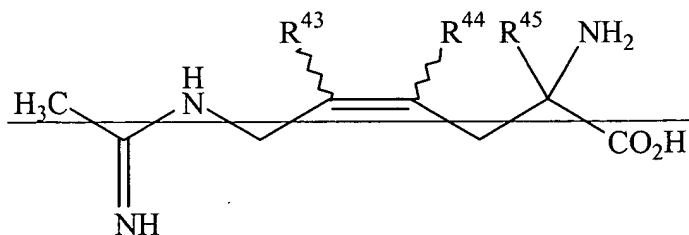
R^{41} is H or methyl; and

R^{42} is H or methyl;

~~a compound of formula IV~~



~~a compound of Formula V:~~



V

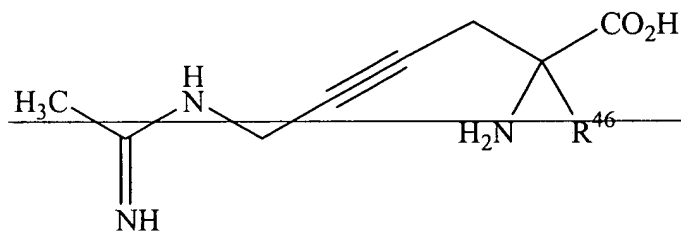
wherein:

~~R⁴³ is selected from the group consisting of hydrogen, halo, C₄-C₅ alkyl and C₄-C₅ alkyl substituted by alkoxy or one or more halo;~~

~~R⁴⁴ is selected from the group consisting of hydrogen, halo, C₄-C₅ alkyl and C₄-C₅ alkyl substituted by alkoxy or one or more halo;~~

~~R⁴⁵ is C₄-C₅ alkyl or C₄-C₅ alkyl substituted by alkoxy or one or more halo;~~

~~a compound of Formula VI:~~

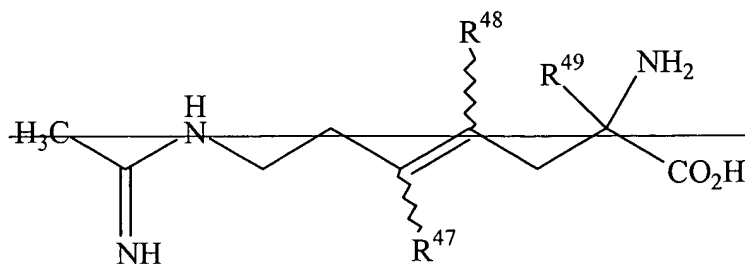


VI

wherein:

~~R⁴⁶ is C₄-C₅ alkyl, said C₄-C₅ alkyl optionally substituted by halo or alkoxy, said alkoxy optionally substituted by one or more halo;~~

~~a compound of Formula VII~~



VII

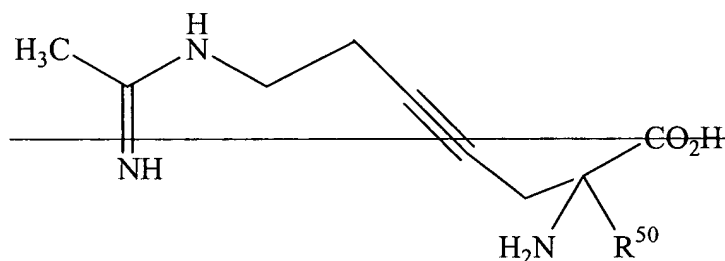
wherein:

~~R⁴⁷ is selected from the group consisting of hydrogen, halo, C₄-C₅ alkyl and C₄-C₅ alkyl substituted by alkoxy or one or more halo;~~

~~R⁴⁸ is selected from the group consisting of hydrogen, halo, C₄-C₅ alkyl and C₄-C₅ alkyl substituted by alkoxy or one or more halo;~~

~~R⁴⁹ is C₄-C₅ alkyl or C₄-C₅ alkyl substituted by alkoxy or one or more halo;~~

~~— a compound of Formula VIII~~

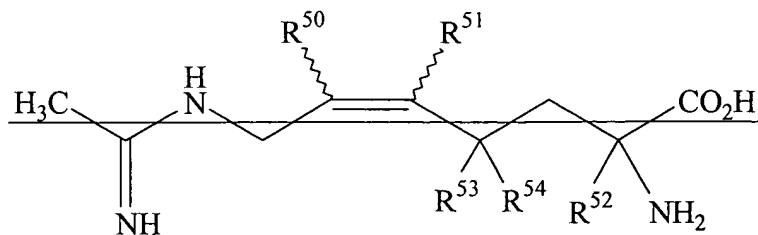


VIII

wherein:

~~R⁵⁰ is C₄-C₅ alkyl, said C₄-C₅ alkyl optionally substituted by halo or alkoxy, said alkoxy optionally substituted by one or more halo;~~

~~a compound of formula IX~~



IX

wherein:

~~R⁵⁰ is selected from the group consisting of hydrogen, halo, and C₄-C₅ alkyl, said C₄-C₅ alkyl optionally substituted by halo or alkoxy, said alkoxy optionally substituted by one or more halo;~~

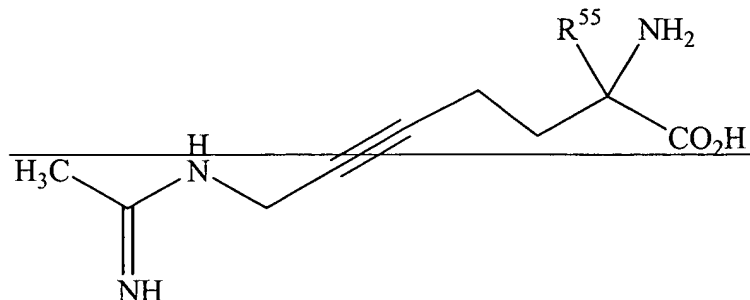
~~R⁵¹ is selected from the group consisting of hydrogen, halo, and C₄-C₅ alkyl, said C₄-C₅ alkyl optionally substituted by halo or alkoxy, said alkoxy optionally substituted by one or more halo;~~

~~R⁵² is C₄-C₅ alkyl, said C₄-C₅ alkyl optionally substituted by halo or alkoxy, said alkoxy optionally substituted by one or more halo;~~

~~R⁵³ is selected from the group consisting of hydrogen, halo, and C₄-C₅ alkyl, said C₄-C₅ alkyl optionally substituted by halo or alkoxy, said alkoxy optionally substituted by one or more halo; and~~

~~R⁵⁴ is selected from the group consisting of halo and C₄-C₅ alkyl, said C₄-C₅ alkyl optionally substituted by halo or alkoxy, said alkoxy optionally substituted by one or more halo;~~

a compound of formula X

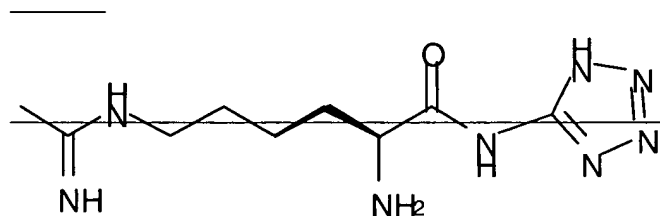


X

wherein:

~~R⁵⁵ is C₄-C₅ alkyl, said C₄-C₅ alkyl optionally substituted by halo or alkoxy, said alkoxy optionally substituted by one or more halo.~~

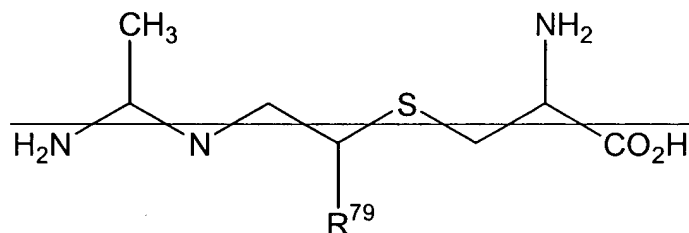
~~a compound having the formula XI~~



2S-amino-6-[(1-iminoethyl)amino]-N-(1H-tetrazol-5-yl) hexanamide, hydrate, dihydrochloride

XI

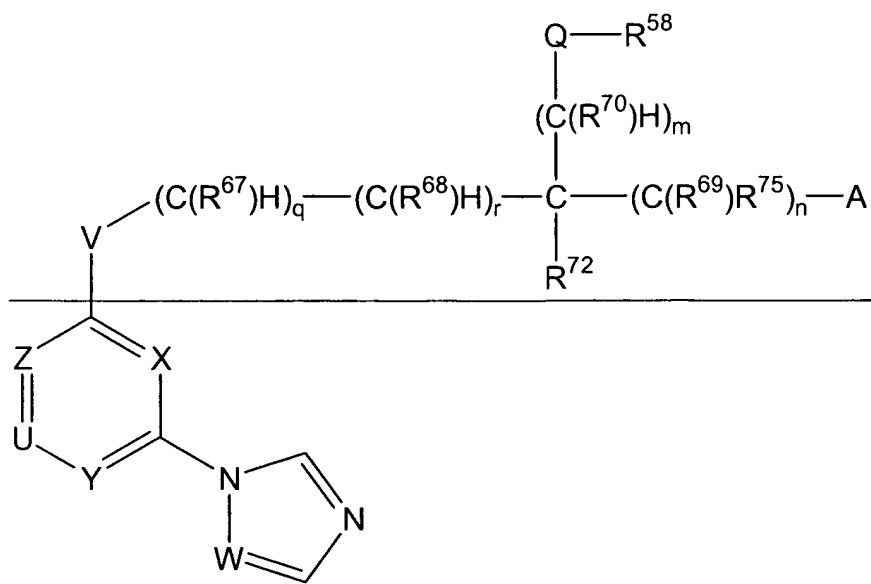
~~A compound of formula XII:~~



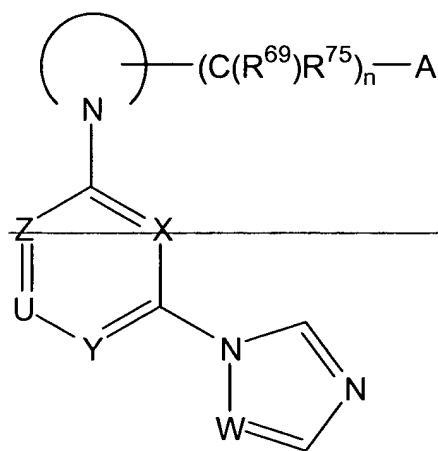
XII

~~wherein R⁷⁹ is selected from C₁₋₄ alkyl, C₃₋₄ cycloalkyl, C₁₋₄ hydroxyalkyl, and C₁₋₄ haloalkyl;~~

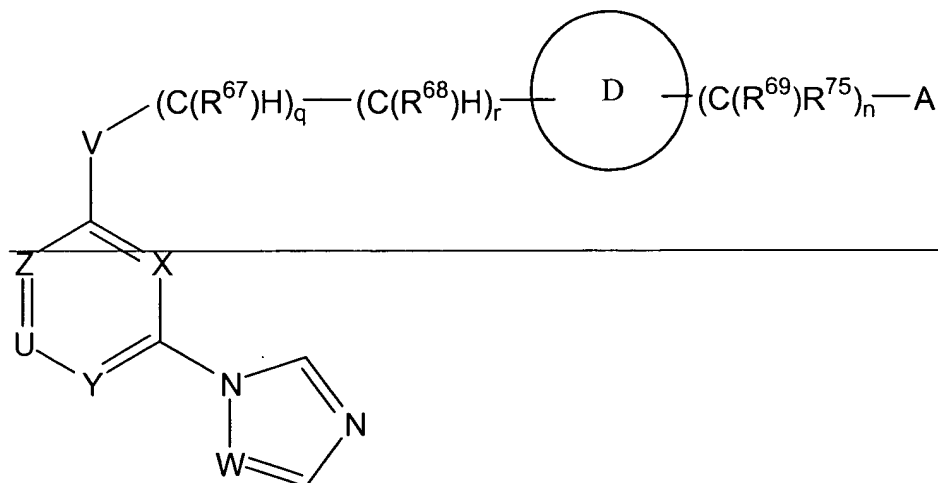
~~a compound of Formula XIII, Formula XIV or Formula XV:~~



Formula XIII;



Formula XIV; or



Formula XV;

wherein:

A is R^{56} , OR^{56} , $\text{C(O)N(R}^{56}\text{)R}^{57}$, $\text{P(O)[N(R}^{56}\text{)R}^{57}]_2$, $\text{N(R}^{56}\text{)C(O)R}^{57}$, $\text{N(R}^{76}\text{)C(O)OR}^{56}$, $\text{N(R}^{56}\text{)R}^{76}$, $\text{N(R}^{74}\text{)C(O)N(R}^{56}\text{)R}^{74}$, $\text{S(O)}_t\text{R}^{56}$, $\text{SO}_2\text{NHC(O)R}^{56}$, $\text{NHSO}_2\text{R}^{77}$, $\text{SO}_2\text{NH(R}^{56}\text{)H}$, $\text{C(O)NHSO}_2\text{R}^{77}$, and CH=NOR^{56} ;

each X, Y and Z are independently N or $\text{C(R}^{49}\text{)}$;

each U is N or $\text{C(R}^{60}\text{)}$, provided that U is N only when X is N and Z and Y are CR^{74} ;

V is $\text{N(R}^{59}\text{)}$, S, O or $\text{C(R}^{59}\text{)H}$;

Each W is N or CH;

Q is chosen from the group consisting of a direct bond, C(O) , O, $\text{C(=N-R}^{56}\text{)}$, S(O)_t , and $\text{N(R}^{61}\text{)}$;

m is zero or an integer from 1 to 4;

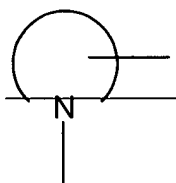
n is zero or an integer from 1 to 3;

q is zero or one;

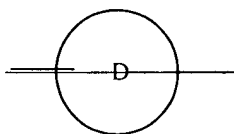
r is zero or one, provided that when Q and V are heteroatoms, m, q, and r cannot all be zero;

when A is OR^{56} , $\text{N(R}^{56}\text{)C(O)R}^{57}$, $\text{N(R}^{74}\text{)C(O)OR}^{57}$, $\text{N(R}^{56}\text{)R}^{76}$, $\text{N(R}^{74}\text{)C(O)N(R}^{56}\text{)R}^{74}$, $\text{S(O)}_t\text{R}^{56}$ (where t is zero), or $\text{NHSO}_2\text{R}^{77}$, n, q, and r

~~cannot all be zero; and when Q is a heteroatom and A is OR^{56} ,
 $\text{N(R}^{56})\text{C(O)R}^{57}$, $\text{N(R}^{74})\text{C(O)OR}^{57}$, $\text{N(R}^{56})\text{R}^{76}$, $\text{N(R}^{74})\text{C(O)N(R}^{56})\text{R}^{74}$, $\text{S(O)}_t\text{R}^{56}$
 (when t is zero), or $\text{NHSO}_2\text{R}^{77}$, m and n cannot both be zero;
 t is zero, one or two;~~



~~is an optionally substituted N-heterocyclyl;~~



~~is an optionally substituted carbocyclyl or optionally
 substituted N-heterocyclyl;~~

~~each R^{56} and R^{57} are independently chosen from the group consisting of
 hydrogen, optionally substituted $\text{C}_1\text{-C}_{20}$ alkyl, optionally substituted
 cycloalkyl,~~

~~$\text{[C}_0\text{-C}_8\text{ alkyl]R}^{64}$, $\text{[C}_2\text{-C}_8\text{ alkenyl]R}^{64}$, $\text{[C}_2\text{-C}_8\text{ alkynyl]R}^{64}$, $\text{[C}_2\text{-C}_8\text{ alkyl]R}^{65}$
 (optionally substituted by hydroxy), $\text{[C}_4\text{-C}_8\text{]R}^{66}$ (optionally substituted by
 hydroxy), optionally substituted heterocyclyl;~~

~~or R^{56} and R^{57} together with the nitrogen atom to which they are attached is
 an optionally substituted N-heterocyclyl;~~

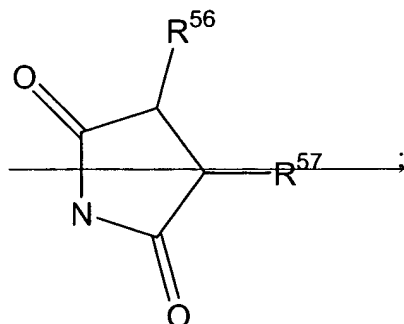
~~R^{58} is chosen from the group consisting of hydrogen, alkyl, cycloalkyl,
 optionally substituted aryl, haloalkyl, $\text{[C}_4\text{-C}_8\text{ alkyl]C(O)N(R}^{56})\text{R}^{57}$,~~

~~$\text{[C}_4\text{-C}_8\text{ alkyl]N(R}^{56})\text{R}^{57}$, $\text{[C}_4\text{-C}_8\text{ alkyl]R}^{63}$, $\text{[C}_2\text{-C}_8\text{ alk2yl]R}^{65}$,~~

~~$\text{[C}_4\text{-C}_8\text{ alkyl]R}^{66}$, and heterocyclyl (optionally substituted by one or more
 substitutents selected from the group consisting of halo, alkyl, alkoxy and
 imidazolyl);~~

~~or when Q is $\text{N(R}^{58})$ or a direct bond to R^{58} , R^{58} may additionally be
 aminocarbonyl,~~

~~alkoxycarbonyl, alkylsulfonyl, monoalkylaminocarbonyl,
 dialkylaminocarbonyl and $\text{C}(=\text{NR}^{73})\text{-NH}_2$;
 or Q-R^{58} taken together represents $\text{C}(\text{O})\text{OH}$, $\text{C}(\text{O})\text{N}(\text{R}^{56})\text{R}^{57}$ or~~



~~R^{59} is chosen from the group consisting of hydrogen, alkyl, aryl, aralkyl and cycloalkyl;~~

~~Provided that when A is R^{56} or OR^{56} , R^{59} cannot be hydrogen, and when V is CH, R^{59} may additionally be hydroxy;~~

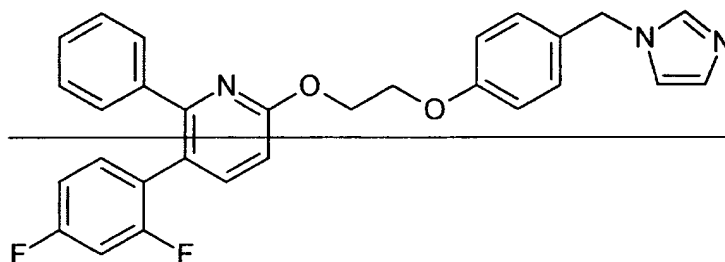
~~R^{60} is chosen from the group consisting of hydrogen, alkyl, aryl, aralkyl, haloalkyl,~~

~~optionally substituted aralkyl, optionally substituted aryl, OR^{74} , $\text{S}(\text{O})_t\text{-R}^{74}$, $\text{N}(\text{R}^{74})\text{R}^{76}$, $\text{N}(\text{R}^{74})\text{C}(\text{O})\text{N}(\text{R}^{56})\text{R}^{74}$, $\text{N}(\text{R}^{74})\text{C}(\text{O})\text{OR}^{74}$, $\text{N}(\text{R}^{74})\text{C}(\text{O})\text{-R}^{74}$, $[\text{C}_0\text{-C}_8$ alkyl] $\text{-C}(\text{H})[\text{C}(\text{O})\text{R}^{74}]_2$ and $[\text{C}_0\text{-C}_8$ alkyl] $\text{-C}(\text{O})\text{N}(\text{R}^{56})\text{R}^{74}$;~~

~~R^{61} is chosen from the group consisting of hydrogen, alkyl, cycloalkyl, $[\text{C}_4\text{-C}_8$ alkyl] -R^{63} , $[\text{C}_2\text{-C}_8]$ alkyl -R^{65} , $[\text{C}_4\text{-C}_8$ alkyl] -R^{66} , acyl, $\text{C}(\text{O})\text{R}^{63}$, $\text{C}(\text{O})\text{-}[\text{C}_4\text{-C}_8$ alkyl] -R^{63} , alkoxycarbonyl, optionally substituted aryloxy carbonyl, optionally substituted aralkoxy carbonyl, alkylsulfonyl, optionally substituted aryl, optionally substituted heterocyclyl, alkoxycarbonylalkyl, carboxyalkyl, optionally substituted arylsulfonyl, aminocarbonyl, monoalkylaminocarbonyl, dialkylaminocarbonyl, optionally substituted arylaminocarbonyl, aminosulfonyl, monoalkylaminosulfonyl, dialkylaminosulfonyl, arylaminosulfonyl, arylsulfonylaminocarbonyl, optionally substituted N-heterocyclyl, $\text{C}(=\text{NH})\text{-N}(\text{CN})\text{R}^{56}$, $\text{C}(\text{O})\text{R}^{78}\text{-N}(\text{R}^{56})\text{R}^{57}$, $\text{C}(\text{O})\text{-N}(\text{R}^{56})\text{R}^{78}\text{-C}(\text{O})\text{OR}^{56}$;~~

~~each R⁶³ and R⁶⁴ are independently chosen from the group consisting of haloalkyl, cycloalkyl, (optionally substituted with halo, cyano, alkyl or alkoxy), carbocyclyl (optionally substituted with one or more substituents selected from the group consisting of halo, alkyl and alkoxy) and heterocyclyl (optionally substituted with alkyl, aralkyl or alkoxy);~~
~~each R⁶⁵ is independently chosen from the group consisting of halo, alkoxy, optionally substituted aryloxy, optionally substituted aralkoxy, optionally substituted -S(O)-, R⁷⁷, acylamino, amino, monoalkylamino, dialkylamino, (triphenylmethyl)amino, hydroxy, mercapto, alkylsulfonamido;~~
~~each R⁶⁶ is independently chosen from the group consisting of cyano, di(alkoxy)alkyl, carboxy, alkoxycarbonyl, aminocarbonyl, monoalkylaminocarbonyl and dialkylaminocarbonyl;~~
~~each R⁶⁷, R⁶⁸, R⁶⁹, R⁷⁰, R⁷², and R⁷⁵ are independently hydrogen or alkyl;~~
~~each R⁷¹ is independently hydrogen, alkyl, optionally substituted aryl, optionally substituted aralkyl or cycloalkyl;~~
~~R⁷³ is hydrogen, NO₂, or toluenesulfonyl;~~
~~each R⁷⁴ is independently hydrogen, alkyl (optionally substituted with hydroxy), cyclopropyl, halo or haloalkyl;~~
~~each R⁷⁶ is independently hydrogen, alkyl, cycloalkyl, optionally substituted aryl, optionally substituted aralkyl, -C(O)R⁷⁷ or -SO₂R⁷⁷; or R⁷⁶ taken together with R⁵⁶ and the nitrogen to which they are attached is an optionally substituted N-heterocyclyl;~~

~~or R⁷⁶ taken together with R⁷⁴ and the nitrogen to which they are attached is an optionally substituted N-heterocyclyl;~~
~~each R⁷⁷ is independently alkyl, cycloalkyl, optionally substituted aryl or optionally substituted aralkyl; and~~
~~R⁷⁸ is an amino acid residue; and~~



PPA250

or a pharmaceutically acceptable salt or prodrug of any of said inducible nitric oxide synthase inhibitors.

Claim 23. (original) The method of Claim 22 wherein the antimicrobial compound comprises an antibiotic compound.

Claim 24 (original) The method of Claim 22 wherein the antimicrobial compound comprises at least one compound selected from the group consisting of the following: amoxicillin, clarithromycin, rifabutin, bismuth subsalicylate, metronidazole, and tetracycline.

Claim 25 (original) The method of Claim 22 further comprising administering to the subject an amount of an antisecretory compound or pharmaceutically acceptable salt thereof or prodrug thereof, wherein the amount of the inducible nitric oxide synthase selective inhibitor, the amount of the antibiotic compound and the amount of the antisecretory compound together

constitute an amount effective against the condition or disease of the gastrointestinal tract.

Claim 26 (original) The method of Claim 25 wherein the antisecretory compound comprises a proton-pump inhibitor.

Claim 27 (original) The method of Claim 26 wherein the antisecretory compound comprises omeprazole.

Claim 28 (original) The method of Claim 25 wherein the antisecretory compound comprises an H₂ receptor antagonist.

Claim 29 (original) The method of Claim 28 wherein the antisecretory compound comprises ranitidine.

Claim 30. (original) The method of Claim 22 wherein the antimicrobial compound comprises a double anti-microbial composition consisting of a combination of two compounds selected from the group consisting of the following: amoxicillin, clarithromycin, rifabutin, bismuth subsalicylate, metronidazole, and tetracycline.

Claim 31 (original) The method of Claim 22 wherein the condition or disease of the gastrointestinal tract is selected from the group consisting of inflammatory bowel disease, Crohn's disease, ulcerative colitis, peptic ulcer disease, gastric ulceration, duodenal ulceration, esophagitis, gastritis, ileitis, colitis, gastroesophageal reflux disease, irritable bowel syndrome, irritable bowel syndrome, paralytic ileus and diarrhea.

Claim 32 (original) The method of Claim 22 wherein the condition or disease of the gastrointestinal tract is inflammatory bowel disease.

Claim 33 (original) The method of claim 22 wherein the condition or disease of the gastrointestinal tract is Crohn's disease.

Claim 34 (original) The method of claim 22 wherein the condition or disease of the gastrointestinal tract is ulcerative colitis.

Claim 35 (original) The method of claim 22 wherein the condition or disease of the gastrointestinal tract is peptic ulcer disease.

Claim 36. (original) The method of claim 35 wherein the condition or disease of the gastrointestinal tract is gastric ulceration.

Claim 37 (currently amended) The method of claim ~~235~~ 22 wherein the condition or disease of the gastrointestinal tract is duodenal ulceration.

Claim 38 (original) The method of claim 22 wherein the condition or disease of the gastrointestinal tract is gastritis.

Claim 39 (original) The method of claim 22 wherein the condition or disease of the gastrointestinal tract is ileitis.

Claim 40 (original) The method of claim 22 wherein the condition or disease of the gastrointestinal tract is colitis.

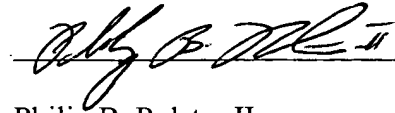
Claim 41 (original) The method of claim 22 wherein the condition or disease of the gastrointestinal tract is esophagitis.

Claim 42 (original) The method of claim 22 wherein the condition or disease of the gastrointestinal tract is gastroesophageal reflux disease.

Claim 43 (original) The method of claim 22 wherein the condition or disease of the gastrointestinal tract is irritable bowel syndrome.

U.S. Serial No. 10/626,941
Amendment Dated 8 October 20, 2004
Response of Office Action mailed November 1, 2004

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Philip B. Polster II", written over a horizontal line.

Philip B. Polster II
Reg. No. 43,864
(314) 274-9094
(314) 274-9095 (facsimile)

Pharmacia Corporation
Corporate Patent Department
P.O. Box 1027
Chesterfield, Missouri 63006